

DECLARATION OF CONFORMITY

MANUFACTURER Qingdao Hightop Biotech Co., Ltd.
No.369 Hedong Road, Hi-tech Industrial Development Zone,
Qingdao, Shandong, 266112, China

EUROPEAN REPRESENTATIVE MedNet EC-REP GmbH
Borkstrasse 10 · 48163 Muenster · Germany

PRODUCT SARS-CoV-2/Flu A+B/AdV/RSV Antigen Rapid Test
--- Analyte: SARS-CoV-2 Antigen, Flu A+B Antigen,
AdV antigen, RSV antigen

CLASSIFICATION Others

CONFORMITY ASSESSMENT ROUTE IVDD 98/79/EC Annex III (Excluding 6)

WE, THE MANUFACTURER, IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY. WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC. ALL SUPPORTING DOCUMENTATIONS ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED 98/79/EC, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN 13612: 2002, EN ISO 23640:2015, EN 13641: 2002, EN ISO 15223-1: 2016, EN 13975:2003, EN ISO 14971:2012, EN ISO 13485: 2016, EN ISO 17511: 2003, EN 62366-1:2015.

PLACE, DATE OF ISSUE Qingdao, 2020-12-23

SIGNATURE


Mr. Frank Yang
General Manager

